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EXAMINER

MENON, KRISHNAN S

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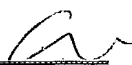
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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 0104

Application Number: 09/806,322
Filing Date: June 05, 2001
Appellant(s): BORMANN ET AL.

MAILED
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Jeremy M. Jay
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/5/04.

(1) *Real Party in Interest*

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A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The Appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The Appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1,2,4-7,9-14 and 17-25 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

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(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1,2,4-7, 9-14 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pall et al (US 5,587,070).

Instant Claim 1: Pall (070) teaches a housing with inlet and outlet having a filter disposed inside (114-fig 4, 12-fig 1, fig 5, col 18 line 54-col 19 line 2, col 27 lines 16-25, claim 1); filter comprising porous fibrous leukocyte depletion medium having CWST >70 dynes/cm (col 13 lines 10-28, col 14 lines 36-40, claims 13 and 14), a second filter of 5 micron or less (col 21 lines 30-43) and which allows plasma to go through but prevents RBCs and leucocytes (col 6 lines 35-43, col 7 lines 15-20, col 11 lines 12-17, claim 1); and as in instant claim 1.

Pall (070), while teaching combination of filter media that prevent red cells and leukocytes from passing through (col 11 lines 11-17; col 10 lines 21-39; col 30 lines 16-35), is not clear whether the first fibrous leukocyte depletion filter and the second membrane filter are integral in one filter housing. However, it would be obvious to one of ordinary skill in the art at the time of invention to put the first filter and the membrane in the same housing in series to obtain the desired separation of biological fluids while reducing the volume hold-up of the biological fluids (col 28 lines 45-52 – implied concern of hold-up volume), and having compactness, ease of fabrication, and less conduit length.

Claims 4-7,9,17,18 and 24, all depending from1, and have additional limitations, which are taught by Pall as follows: filter element comprises melt-blown fibers as in

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instant claim 4 (col 18 lines 17-30); first filter at least two layers (col 33 lines 18-21) as in instant claim 5, CWST >90 dynes/cm as in instant claim 6(see table, and claim 14); first and second containers with filter interposed in between as in instant claim 9(see figures); second filter is a membrane of pore size 0.3- 3 microns (col 21 lines 30-43) as in instant claim 17 and 18; can be arranged to allow platelets to pass as in instant claim 24 (col 6 lines 35-43).

Independent Claim 2 has an added limitation to that recited in claim 1, fibrous red cell barrier (col 11 lines 11-17); claim 19, dependent on claim 2, has the added limitation: second filter is a membrane of pore size 0.3- 3 microns (see col 21 lines 30-43); and claim 25, dependent on claim 2, has the added limitation: the filter being arranged to substantially prevent passage of platelets (see col 18 lines 34-42), all taught by Pall.

Independent Claim 20 has an added limitation to what is recited in claim 2, that is, the filter includes no more than one membrane, which is also taught by Pall (col 11 lines 11-17).

Method claims 10 and 11(both independent): Pall teaches a method of processing a biological fluid comprising passing a red blood cell and leukocyte containing plasma rich biological fluid into a filter device comprising a leukocyte depletion medium and a membrane, and collecting a filtered plasma-rich fluid substantially free of leukocytes and red cells as in instant claims 10 (abstract and fig 1). Claim 11 has the added limitation that the biological fluid to be processed is leukocyte containing plasma-rich biological fluid.

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Pall (070), while teaching combination of filter media that prevent red cells and leukocytes from passing through (col 11 lines 11-17; col 10 lines 21-39; col 30 lines 16-35), is not clear whether the first fibrous leukocyte depletion filter and the second membrane filter are integral in one filter housing for the process of instant claim 10 and 11. However, it would be obvious to one of ordinary skill in the art at the time of invention to put the first filter and the membrane in the same housing in series to obtain the desired separation of biological fluids while reducing the volume hold-up of the biological fluids (col 28 lines 45-52 – implied concern of hold-up volume), and having compactness, ease of fabrication, and less conduit length.

Method Claims 12, independent, and 13 depending from 12 have the added limitations to what is recited in claim 11: processing a biological fluid to provide a supernatant layer comprising a leukocyte containing plasma-rich fluid and sediment layer containing a red blood cell containing fluid (col 1 line 62 – col 2 line 63) as in instant claim 12 and wherein the leukocyte containing plasma rich fluid comprises a leukocyte and platelet depleted biological fluid as in claim 13 (col 2 lines 35-42), all taught by Pall.

Method claim 14 (independent): Pall teaches a method of processing a biological fluid comprising depleting leukocytes and platelets from blood to provide a red blood cell containing fluid, processing the red blood cell containing fluid to provide a supernatant layer containing plasma and sediment layer containing red blood cells (see col 1 line 62-col 2 line 53), passing the supernatant layer through a filter comprising a housing with inlet and outlet having a filter disposed inside (114-fig 4, 12-fig 1, fig 5, col

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18 line 54-col 19 line 2, col 27 lines 16-25, claim 1); filter comprising porous fibrous leukocyte depletion medium having CWST >70 dynes/cm (col 13 lines 10-28, col 14 lines 36-40, claims 13 and 14), a second filter of 5 micron or less (col 21 lines 30-43) and which allows plasma to go through but prevents RBCs and leucocytes (col 6 lines 35-43, col 7 lines 15-20, col 11 lines 12-17, claim 1); and collecting the plasma-rich fluid down-stream of the filter device (fig 1)

Pall (070), while teaching combination of filter media that prevent red cells and leukocytes from passing through (col 11 lines 11-17; col 10 lines 21-39; col 30 lines 16-35), is not clear whether the first fibrous leukocyte depletion filter and the second membrane filter are integral in one filter housing for the process of instant claim 14. However, it would be obvious to one of ordinary skill in the art at the time of invention to put the first filter and the membrane in the same housing in series to obtain the desired separation of biological fluids while reducing the volume hold-up of the biological fluids (col 28 lines 45-52 – implied concern of hold-up volume), and having compactness, ease of fabrication, and less conduit length.

Method claim 21 and 22 and 23 depending from 21: Pall (070) teaches the method of processing a biological fluid through a filter (abstract, fig 1), the filter comprising a housing with inlet and outlet having a filter disposed inside (114-fig 4, 12-fig 1, fig 5, col 18 line 54-col 19 line 2, col 27 lines 16-25, claim 1); filter comprising porous fibrous leukocyte depletion medium having CWST >70 dynes/cm (col 13 lines 10-28, col 14 lines 36-40, claims 13 and 14), a second filter of 0.3 to 3 microns downstream of first (col 21 lines 30-43) and which allows plasma to go through but prevents

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RBCs and leucocytes (col 6 lines 35-43, col 7 lines 15-20, col 11 lines 12-17, claim 1); claim 22 has the added limitation that the filter also depletes platelets (col 21 lines 30-43).

Pall (070), while teaching combination of filter media that prevent red cells and leukocytes from passing through (col 11 lines 11-17; col 10 lines 21-39; col 30 lines 16-35), is not clear whether the first fibrous leukocyte depletion filter and the second membrane filter are integral in one filter housing for the process of claims 21-23.

However, it would be obvious to one of ordinary skill in the art at the time of invention to put the first filter and the membrane in the same housing in series to obtain the desired separation of biological fluids while reducing the volume hold-up of the biological fluids (col 28 lines 45-52 – implied concern of hold-up volume), and having compactness, ease of fabrication, and less conduit length. Pall also does not teach the volume of fluid to be 500-1000 ml as in the claim 23. However, Pall teaches a filter that could filter 450 ml (Pall '070: col 6 lines 3-9) and it would be obvious to one of ordinary skill in the art at the time of invention that this filter could filter a larger volume with a longer duration of filtering.

(11) Response to Argument

Appellant's arguments are not commensurate in scope with the claims, and are based on limitations not recited in the claims.

Independent claim 1 recites a leukocyte depletion medium and a membrane of 5-micron pore size in one housing with inlets and outlets, and arranged to allow plasma to pass through and retain leukocytes and red blood cells. Independent claim 2 recites a

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leukocyte depletion *and red cell* barrier medium, and a membrane of 5-micron pore size in one housing with inlets and outlets, and arranged to allow plasma to pass through and retain leukocytes.

Pall teaches the inventions in claims 1 and 2, except that the 5-micron membrane filter is not housed in the same housing with the leukocyte depletion (and red cell barrier) medium. However, if one puts the entire assembly of the Pall ref (fig 2) in one box and provide an inlet and an outlet to the box, it would read into the claims.

Appellant argues that the office action had converted the tangential flow non-centrifugal separation device of Pall '070 into a perpendicular flow device; and that such force fitting was not correct. In response: *the claims do not recite the limitation "a perpendicular flow"* for the 5-micron membrane or the leukocyte depletion medium for the office action to make such a conversion. Also, a perpendicular flow leukocyte depletion/red cell barrier medium could be fitted in to a housing which has a tangential flow membrane filter by simple engineering design.

Appellant argues further about the impropriety of having a fibrous leukocyte depletion medium in a separation device containing a tangential flow membrane with the concern that such an arrangement would interfere with the tangential flow system. Here again, the Appellant takes into consideration limitations that are not recited in the claim: Claims are not limited to any specific structure or arrangement of the leukocyte depletion medium and the membrane inside the housing for this argument to be relevant. Claims recite that the leukocyte depletion medium and the membrane are in one housing, claims are open-ended (comprising language), and there is nothing in the

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claims that prevent the filters within the housing to be separated from each other by containment, orientation, flow geometry or other design parameters.

In contrast to the Appellant's arguments, the office action has not suggested modifying the flow-paths through the leukocyte depletion medium or the membrane, since the claims do not have any limitations that warrant such modifications.

Another argument the Appellant makes is that there is no suggestion to combine the leukocyte depletion medium and the "non-centrifugal separation device" (which is essentially the 5-micron membrane in a housing and having tangential flow) in one housing, that the office action improperly used Appellant's disclosures as a template to select elements from the recited reference for the basis of rejection, and quoted a case law, *In re Gorman*, 933 F.2d 982, 18 USPQ 2d 1885 (Fed. Cir. 1991). In response: Examiner believes that this case law has no bearing on the present case. The case law is about combining a large number of references in order to support a rejection of obviousness. The present case is about a single reference and whether there is any explicit or implied suggestion to combine the filters into one housing. Re explicit or implied suggestions to combine, Pall'070 teaches a system combining the elements recited in the claim (see abstract). In col 6 line 63 – col 7 line 20, Pall'070 teaches "filter assembly ... in a suitable housing ...", "... filter assembly may include a leukocyte depletion medium, red cell barrier, ..., porous medium may be configured as flat sheet, ... hollow fiber, ..., separation medium ...". Col 10 lines 21-40 teaches separating plasma from blood (as claimed in claims 1 and 2) using a separation medium. Col 12 lines 30-35 teaches the possibility of combination of assemblies, media, containers and

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conduits. Thus Pall reference contemplates on many possible alternatives for the design. It may also be noted that making integral, as in combining the filters into one housing, would be an obvious engineering choice. ["...the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice" (*In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965))]

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Krishnan Menon
Patent Examiner

January 22, 2004


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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

Application/Control Number: 09/806,322

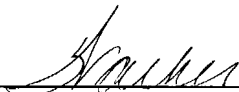
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